

GMP Training Workshop

April 22, 2010—Doubletree Hotel—Boston/Waltham, MA



Effective Generation and Control of Master Production Batch Records (MPBR)

Presented by

enKap
ENGAGED KNOWLEDGE APPLICATION

Publisher of



This Training Workshop Features “Hands On” Application Exercises

7:30 a.m.

Registration/Continental Breakfast

8:30 a.m.—9:30 a.m.

Fundamentals: What is Needed and Why

Fundamental requirements of a Master Production Batch Record (MPBR) can appear straight forward, but we will discuss the skills and resources necessary to create an effective document.

- Workshop scope and objectives
- MPBR functions
- Terminology

9:30 a.m.—10:15 a.m.

Regulatory requirements of an MPBR

Understanding regulatory requirements (FDA and MHRA) is essential when creating the MPBR.

- Examination and understanding of requirements
- Company requirements
- Generation and usefulness of the checklist as a tool to ensure completeness and consistency of content

APPLICATION EXERCISE

Creating an MPBR Checklist

10:15 a.m.—10:30 a.m.

Morning break

10:30 a.m.—11:30 a.m.

How to Effectively Use Templates During the Preparation of the MPBR.

- Template design considerations
- Must haves: adequate space, clear and concise instructions, etc.

- Obtaining operator input and buy-in
- Examining approvers requirements

APPLICATION EXERCISE

Generating Effective Templates

Practical and effective templates for different operations in manufacturing, packaging and labeling.

11:30 a.m.—12:30 p.m.

Lunch

12:30 p.m.—1:15 p.m.

Effective Communication Skills: Writing Clearly and Concisely

Communication by the author to trained operators via instructions is essential to performing required operations.

- How to clearly communicate
- Effective instructions
- Confirmation of operations
- Explanations clear and simple
- Unclear instructions and ambiguous responses
- Deviations
- Minimizing errors

APPLICATION EXERCISE

Generation of effective written and verbal instructions

1:15 p.m.—2:15 p.m.

Effectively Managing Document Control and Changes to the MPBR

- Controlling the MBPR
- Document access

- Official copies and version control
- Management of change
- History of clinical supplies formulation changes

APPLICATION EXERCISE

Controlling MPBRs for clinical and commercial supplies: requirements

2:15 p.m.—2:30 p.m.

Afternoon Break

2:30 p.m. – 3:15 p.m.

Content Similarities and Differences between Product Requirements

Understanding specific requirements for different products enables an author to generate a practical document that can be effectively utilized by operators.

- Examining similarities and significant differences between clinical supplies Phase I, clinical supplies Phases II to III and commercial products
- Review of special requirements (sterile, oral, topical products, etc.)

APPLICATION EXERCISE

Develop a comparison chart to support MPBR generation

3:15 p.m.—4:00 p.m.

MPBR Standard Operating Procedure: Providing Direction and Control

Training: How can this be managed effectively and efficiently to avoid errors?

Defining SOP content governing MPBRs is essential. Everyone involved in the process must clearly understand their specific responsibilities.

- Generation of the MPBR
- Content and management
- Review and approval
- Access to documents
- Change management
- Training requirements

APPLICATION EXERCISES

Examining key points that must be included in the SOP governing MPBR

Training for new and revised MPBRs

4:00 p.m.—4:30 p.m.

Question and Answer Session

Attendees will have the opportunity to ask the instructor questions. This time can be used to expand on any topic discussed earlier in the day which may be of particular interest to attendees.

Training Concludes

What Attendees Will Learn In This Workshop

- A clear understanding of regulatory requirements
- Clarification and confirmation of terminology
- How to effectively use templates for the generation of records and communication with operators
- How to generate practical documents that support the manufacturing, packaging and labeling operations. How not to over complicate the process with multiple entries, unnecessary transfer of data/information multiple times, and overwhelming operators with signatures and initials with little added value.
- Why master records are critical to the effective and compliant operation of a facility
- How to minimize problems during record execution with adequate planning
- How to determine training requirements based on new and revised records

Integration of theory and discussion with practical exercises enables attendees to practice while the workshop is in session.

An open platform is provided for exchange of questions, information and ideas.

The Facilitator continuously monitors the session to enable the most effective utilization of time and exercises.

Real examples and situations encountered are used to ensure that theory is related to practice at key points.

Attendees are encouraged to submit their questions prior to the workshop, so that focus can be devoted to specific subject areas (time permitting).

Who Should Attend

- Personnel responsible for authoring master records
- Manufacturing Managers responsible for approving master records
- Operators
- QA personnel responsible for approving master records
- Auditors requiring additional insight for key indicators of compliance status
- Document management personnel
- Personnel new to the manufacturing environment wishing to obtain further industry knowledge

General Information

The training workshop fee includes continental breakfast, lunch and all conference materials.

About Your Instructor



Graham Bunn is the President of GB Consulting LLC. His experience includes the following:

- Over 20 years experience in the pharmaceutical industry, primarily in a quality function
- Corporate Auditor for major pharmaceutical companies, including SmithKline Beecham, Wyeth and AstraMerck in both the U.S. and UK
- Broad knowledge of clinical trials and commercial production (sterile/non-sterile) from active pharmaceutical ingredients to finished products in the U.S. & Europe
- Biologicals, pharmaceuticals, dietary supplements and medical devices
- Extensive quality assessment, regulatory action

remediation as a team leader/member and as an individual

- Presentation of numerous conference training workshops and multiple client specific on-site workshops
- Publication of articles and chapters in four core GMP/Compliance books

GB Consulting LLC

Graham provides quality assurance and compliance support for FDA-regulated companies. His clients range from virtual companies of less than 20 to multi-national sites of several hundred employees. He also specializes in unique highly interactive client workshops focused on specific site requirements in an active learning environment. Workshops are created specifically for each client with extensive planning and input from key site personnel.

GMP Training Workshop Venue

April 22, 2010
 Doubletree Guest Suites Hotel Boston/Waltham, MA
 550 Winter St.
 Waltham, MA 02451
 781-890-6767

[Doubletree Guest Suites Hotel](#)



FDA COMPLIANCE DIGEST

To view our November 2009 Sample Issue or November 2009 Premier Issue article excerpts click on the links below.

FDA Compliance Digest November 2009

Sample Issue: [click here](#)

FDA Compliance Digest November 2009

Premier Issue article excerpts: [click here](#)

Exclusive GMP, GCP and GLP Editorial Lineup:

The January 2010 Issue will include the following “How To” Meet FDA Requirements Articles, Checklists, SOPs and PowerPoint Training Presentations:

- Complaint Handling
- CAPA
- Ensuring GCP Quality in Your Clinical Trial
- Informed Consent
- Computer Validation Requirements
- SOP on SOPs
- Part 11 Compliance Assessment Checklist
- Good Documentation Practice
- Subpart B of the Drug GMP Regulations
- GLP Regulations

Mission Statement:

enKap provides an exclusive learning community for professionals in FDA-regulated industry to continuously strengthen and apply their foundation of knowledge related to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Our training workshops are based on the principle of engaging learners through a variety of active learning and instructional activities.

Registration Form

GMP Training Workshop

April 22, 2010

Doubletree Guest Suites Hotel Boston/Waltham, MA

Training Workshop Fee - \$550.00



Effective Generation and Control of Master Production Batch Records

Four easy ways to register:

1. Call: 561-795-2785
2. Online: <http://www.enkap.com>
3. Fax this completed form: 561-798-8138
4. Mail this completed form: enKap, 125 South State Road 7, Suite 104-222, Wellington, FL 33414

Contact Information

Last Name:	First Name:	M.I.:	
Job Title:			
Department:		Company:	
Mailing Address:			
City:	State/Province:	Zip/Postal Code:	Country:
Business Phone:		Fax:	

PAYMENT

Enclosed find my payment of \$ _____
All payments must be in U.S. Dollars. Federal Tax ID #26-4253129

Early Registration Discount: Register for this training workshop by March 5, 2010 and save 10%. After this date, price will be \$550.00.

Credit Card

- American Express MasterCard Visa Discover PayPal

Total Amount:	Credit Card Number:		
Expiration Date:	Security Code (found on back of card):		
Name (exactly as it appears on card):			
Billing Address (if different from above):			
City:	State/Province:	Zip/Postal Code:	Country:
Billing Phone (if different from above):		Signature:	

Check

- Forward together with completed registration form payable to enKap (checks must be in U.S. dollars and drawn on a U.S. bank). No personal checks will be accepted.

Invoice

- Please mark here to request an invoice from enKap. You are not considered registered until payment is received and a confirmation has been sent from enKap.

Refunds: Refund requests must be made in writing and received by April 1, 2010. You will receive a refund, less a \$200.00 cancellation fee. After the above-mentioned date, no refunds will be approved. enKap's liability is limited to refund of the training workshop registration fee only. **Substitutions:** If you are unable to attend, substitutions can be made anytime. **Group Discounts:** Available for three or more individuals from the same facility. Call the enKap community desk toll-free at 1-877-823-4GXP for more details.